IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Stephen W. Boyd	Attorney Docket:	FXH1006USC1
Serial No.:	10/625,145	Group Art Unit:	3731
Filed:	July 22, 2003	Examiner:	Vi X. Nguyen
For:	METHODS AND DEVICES FOR REMOVING MATERIAL FROM A VASCULAR SITE		

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed December 2, 2010 from the Final Rejection of claims 16, 28 to 35, 63, and 64 of the above-identified application, as set forth in the Final Office Action mailed August 3, 2010 and in response to the Notice of Panel Decision from Pre-Appeal Brief Review, mailed January 26, 2011, the period of response to which has been extended to March 26, 2011, by the enclosed Petition for Extension for Period of Response. Please charge our Deposit Account No. 16-2312 in the amount of $670.00 to cover the fee for filing an appeal brief ($540.00) and the fee for a one-month extension of time ($130.00). Appellant respectfully requests reconsideration and reversal of the Examiner's rejection of the pending claims.

Certificate of Electronic Transmission (37 C.F.R. § 1.8)

I hereby certify that this paper is being transmitted to the U.S. Patent and Trademark Office electronic filing system on the date indicated below.

Date: March 28, 2011 **Signature:** /Jodi Jung/

Name: Jodi Jung

As required by 37 C.F.R. § 41.37, this Brief contains the following items under the headings and in the order suggested therein.

TABLE OF CONTENTS

(1) REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Tyco Healthcare Group LP.

(2) RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant or Appellant's representative that will have a bearing on the Board's decision in the present appeal.

(3) STATUS OF CLAIMS

Claims 17 to 27 and 37 to 60 have been canceled. Claims 1 to 16, 28 to 36, and 61 to 64 are pending and claims 1 to 15, 36, 61, and 62 have been withdrawn from consideration. Claims 16, 28 to 35, 63, and 64 are under examination, have been rejected and are the subject of this appeal.

(4) STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action mailed August 3, 2010.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

There are two independent claims, claims 16 and 28, pending and on appeal. Below Appellant provides a summary of the claimed subject matter in accordance with 37 C.F.R. § 41.37(v) with reference to support found in the specification.

Independent claim 16

The invention as recited in claim 16 relates to a device for removing material from a vessel wall at a vascular site (page 1, lines 16 to 17; and FIGS. 1 to 28). The device has a cage which is movable from a collapsed position to an expanded position (page 1, lines 17 to 18; page 5, lines 5 to 6; and FIGS. 2 to 6). The cage has a plurality of openings in the expanded position, the openings being formed by rigidly connected elements (page 1, lines 17 to 18 and lines 22 to 23; and page 5, lines 6 to 8). The cage is configured such that when the cage is in the expanded position at the vascular site material from the vessel wall extends from the vessel wall into the openings (page 1, lines 23 to 25; page 5, lines 11 to 12; and Figs. 6, 7 and 18 to 21). The cage has an inner surface which defines a cavity and the cage is releasable so that the cage may be left within the patient (page 2, lines 14 to 17; and page 3, lines 15 to 16). The device also has a material removing element positioned within the cage cavity to remove the material from the vessel wall extending into the openings when the cage is in the expanded position (page 1, lines 18 to 20; page 2, lines 14 to 20; and page 5, lines 8 to 9). The material removing element is positioned beneath the cage and is configured to be movable along the inner surface of the cage to remove the material extending into the openings (page 2, lines 14 to 20).

Independent claim 28

The invention as recited in claim 28 relates to a device for removing material from a vessel wall at a vascular site (page 1, lines 16 to 17; and FIGS. 1 to 28). The device has a sheath and an expandable cage which is movable from a collapsed position to an expanded position (page 1, lines 17 to 18 and lines 27 to 28; page 5, lines 5 to 6; and FIGS. 2 to 6). The cage forms a plurality of openings in the expanded position (page 1, lines 17 to 18; and page 5, lines 6 to 8). The cage is configured such that when the cage is in the expanded position at the vascular site material from the vessel wall extends from the vessel wall into the openings (page 1, lines 23 to 25; page 5, lines 11 to 12; and Figs. 6, 7 and 18 to 21). The cage has an inner surface which defines a cavity and the cage is contained within the sheath in the collapsed position so that the sheath holds the cage in the collapsed position (page 2, lines 14 to 17; and page 5, lines 22 to 24). The cage is releasable so that the cage may be left within the patient (page 3, lines 15 to 16). The sheath of the device is retractable relative to the cage to expose the cage and permit the cage to expand (page 5, lines 22 to 24). The device also has a material removing element positioned within the cage cavity to remove the material from the vessel wall extending into the openings (page 1, lines 18 to 20; page 2, lines 14 to 20; and page 5, lines 8 to 9). The material removing element is positioned beneath the cage and is configured to be movable along the inner surface of the cage to remove the material extending into the openings (page 2, lines 14 to 20).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(1) Whether claim 16 is unpatentable under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,046 to Passafaro et al. (Passafaro).

(2) Whether claims 63 and 64 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,156,046 to Passafaro et al. (Passafaro) in view of U.S. Patent No. 5,211,651 to Reger et al. (Reger).

(3) Whether claims 28 to 30 and 33 to 35 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,156,046 to Passafaro et al. (Passafaro) in view of U.S. Patent No. 5,776,141 to Klein et al. (Klein).

(4) Whether claims 31 and 32 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,156,046 to Passafaro et al. (Passafaro) in view of U.S. Patent No. 5,776,141 to Klein et al. (Klein) and in further view of U.S. Patent No. 5,211,651 to Reger et al. (Reger).

(7) ARGUMENT

(1) Claim 16.

Claim 16 is directed to a device for removing material from a vessel wall at a vascular site. The device includes an expandable cage which is expanded at the vascular site so that unwanted material extends into openings in the cage. The device further includes a material removing element that is used to remove the unwanted material extending into the openings. Claim 16 is directed to that device and requires that the device comprise both:

(1) an expandable cage, and

(2) a material removing element positioned within a cavity defined by an inner surface of the cage.

The Examiner has rejected claim 16 as being anticipated by Passafaro. The Examiner states that Passafaro discloses in FIGS. 10I to 10M a stent having the features of the cage recited in claim 16 and a material removal element 54 positioned within the cage cavity. Therefore, the Examiner concludes that Passafaro anticipates claim 16.

Appellant respectfully points out, however, that the stent forms no part of the system disclosed by Passafaro. Specifically, Passafaro discloses a material removal system 30 that includes a catheter 32 which has a flexible elongate catheter body 34 having a proximal end 36 and a distal end 38, and defining at least one lumen 50 extending longitudinally therethrough. The catheter is coupled to a hand-held device 42 and a collection reservoir 44. The hand-held device includes a motor for rotating a removal mechanism 54 provided at a distal end 38 of the catheter 32 to extract occluding material. (Passafaro, col. 8, lines 15 to 25). The system disclosed by Passafaro is for removing stenotic material from blood vessels including vessels in which a stent has been previously implanted. (Passafaro, col. 7, lines 18 to 21 and col. 20, lines 1 to 3 and lines 7 to 13). In other words, the system which is disclosed by Passafaro does not include the stent which is described as having been previously implanted, nor does it include any other structure which could be considered to comprise a cage. The stent merely forms a part of the environment in which the system disclosed by Passafaro may be used.

In order to anticipate under 35 U.S.C. § 102 a prior art reference must not only disclose all of the elements of the claim within the four corners of the document but must also disclose those elements "arranged as in the claim". *Net Moneyin v. Versign*, 545 F. 3d 1359, 1369 (Fed. Cir. 2008). In making this rejection the Examiner has combined an element of the removal device disclosed by Passafaro with an element that Passafaro clearly discloses as being an element

(the stent) of a different device which was previously implanted in a different and prior procedure. In other words, the "device" indentified by the Examiner as anticipating claim 16 comprises a stent left at the treatment site during a first treatment procedure and the removal mechanism of Passafaro's device which is used during a second treatment procedure to remove material from within the stent. Clearly, the device disclosed by Passafaro does not include the stent. Further, Passafaro does not disclose a device having the elements of claim 16, as arranged in the claim, which requires a single device that includes both a cage and a material removal element. Therefore, Passafaro does not anticipate claim 16 and Appellant respectfully requests that the rejection be reversed.

Further, claim 16 is allowable for at least two additional reasons. Claim 16 includes at least two features that have not been properly considered by the Examiner. Specifically, claim 16 requires that the cage be (1) "moveable from a collapsed position to an expanded position", and that the cage be (2) "releasable so that the cage may be left within the patient". As noted above, the Examiner considers the stent, which was previously implanted in a separate treatment procedure unrelated to the treatment procedure disclosed by Passafaro using a separate device unrelated to the device disclosed by Passafaro, as being the cage. Further, the Examiner believes that the device which anticipates claim 16 is shown in FIGS. 10I to 10M. In other words, the device identified by the Examiner includes the previously implanted stent S and the material removing element 54 shown at a particular point in time during the use of Passafaro's device. At the time of the procedure described by Passafaro, which is shown in the figures identified by the Examiner, the previously implanted stent has already become occluded with occluding material OM.

Although the stent may have been movable from a collapsed position to an expanded position when it was originally implanted during the first procedure and although it may have been releasable from the separate device used to implant it, the stent is neither expandable nor releasable during the period of time it is associated with Passafaro's material removal element as shown in FIGS. 10I to 10M. In other words, by the time the stent becomes associated in any manner with the material removal device disclosed by Passafaro it is no longer "movable from a collapsed position to an expanded position", it is merely a previously expanded stent that comprises a part of the work environment for Passafaro's material removal device. Further, the stent is not "releasable" from the material removal device disclosed by Passafaro, having already been released, presumably from a stent delivery catheter during the previous procedure. Additionally, the feature of being "releasable" implies that there is some connection to the device which can be released. Passafaro discloses no connection or relationship between the material removal system and the stent other than that the material removal device can be used to remove occluding material from an occluded stent. The stent is in the vessel before, during, and after use of the material removal system described by Passafaro and is not "releasable" from any part or element of that system. Therefore, Passafaro does not anticipate claim 16 for these additional reasons and Appellant requests that the rejection be withdrawn.

(2) Claims 63 and 64.

Claims 63 and 64 depend from independent claim 16. Appellant believes claims 63 and 64 are allowable for at least the reasons set forth above. Reger contains no teaching or disclosure correcting the deficiencies of Passafaro set forth

above. Therefore, Appellant believes claims 63 and 64 are allowable for at least those same reasons.

(3) Claims 28 to 30 and 33 to 35.

Claim 28 is directed to a device for removing material from a vessel wall at a vascular site and comprises a sheath, an expandable and releasable cage and a material removing element positioned within a cavity defined by an inner surface of the cage. The sheath is retractable relative to the cage to expose the cage and permit the cage to expand. As discussed above, Passafaro does not disclose a device which includes a releasable and expandable cage and a material removal element. In the Final Office Action mailed August 3, 2010, the Examiner acknowledges that Passafaro fails to disclose an expandable cage being contained within a sheath and the sheath being retractable relative to the cage to expose or expand the cage. However, on page 4, lines 13 to 15 the Examiner cites Klein as teaching "an expandable cage S being contained within a sheath 70 and the sheath 70 is retractable relative to the cage to expose or expand the cage". The Examiner concludes that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Passafaro with an expandable cage being contained within a sheath and the sheath is retractable relative to the cage to expose or expand the cage in order to deliver a proper stent to intraluminal target sites." (Emphasis supplied).

Appellant submits that a person of skill in the art would not, in view of the combined teaching of Passafaro and Klein, modify the material removal system disclosed in Passafaro to include a stent. The system disclosed by Passafaro is intended to be used to remove occluding material from a body vessel, including occluding material from within a stent which was previously implanted in the

vessel and which, over a period of time, has become occluded. The stent, however, plays no part in the material removal process. As a matter of fact, the stent complicates the process. As stated by Passafaro, "[t]reatment of an occluded stent faces all the difficulties discussed above with respect to treatment of initial occlusions and is further complicated by the need to avoid damaging the stent during the removal of the hyperplasia occluding material." (Passafaro, col. 2, lines 58 to 63). Therefore, a person of skill in the art would have no reason to intentionally incorporate a stent into the system disclosed by Passafaro (or a stent and sheath as disclosed in Klein) since such modification would provide no functional advantage and would, in fact, further complicate use of the device. Additionally, a person of skill in the art would understand that a stent is deployed in a vessel for the purpose of opening and maintaining the patency of the vessel. The person of skill in the art also understands that although some stents will eventually become occluded with occluding material that result is undesirable and does not occur until after the passage of considerable time. Therefore, the person of skill in the art would have no reason to combine a stent delivery catheter with a device to remove occluding material from an implanted stent since the person of skill in the art understands that a stent becomes occluded, if at all, only after the passage of time so there would be no reason to include a material removal device at the time the stent is initially implanted.

Even if the person of skill in the art desired to treat a vessel using both the stent therapy of Klein and the material removal therapy of Passafaro those therapies would not be combined in the manner suggested by the Examiner. Passafaro makes it clear that the presence of a stent makes use of the material removal system more complicated. Therefore, if the person of skill in the art desired to use both forms of treatment the person of skill would first remove occluding material from the vessel with the Passafaro device and then deploy the

stent. Although Appellant submits that neither Passafaro nor Klein teach the combination of such therapies in a single treatment device, Appellant believes that such combination, even if made, would not result in a device having the features of claim 28. For at least these reasons Appellant believes claim 28 is allowable and request that the rejection be withdrawn.

Claims 29, 30 and 33 to 35 depend from independent claim 28. Appellant believes claims 29, 30 and 33 to 35 are allowable for at least the reasons set forth above. Therefore, Appellant believes claims 29, 30 and 33 to 35 are allowable for at least those same reasons.

(4) Claims 31 and 32.

Claims 31 and 32 depend from independent claim 28. Appellant believes claims 31 and 32 are allowable for at least the reasons set forth above. Reger contains no teaching or disclosure correcting the deficiencies of Passafaro and Klein set forth above. Therefore, Appellant believes claims 31 and 32 are allowable for at least those same reasons.

(8) SUMMARY

For the reasons discussed above, claims 16, 28 to 35, 63, and 64 are not properly rejected under 35 U.S.C. § 102(e) or under 35 U.S.C. § 103(a).

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: March 28, 2011

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CLAIMS APPENDIX

16. (Previously presented) A device for removing material from a vessel wall at a vascular site, comprising:

a cage which is movable from a collapsed position to an expanded position, the cage having a plurality of openings in the expanded position, the openings being formed by rigidly connected elements, the cage being configured such that when the cage is in the expanded position at the vascular site material from the vessel wall extends from the vessel wall into the openings, the cage having an inner surface which defines a cavity, the cage being releasable so that the cage may be left within the patient; and

a material removing element positioned within the cage cavity to remove the material from the vessel wall extending into the openings when the cage is in the expanded position, the material removing element being positioned beneath the cage and being configured to be movable along the inner surface of the cage to remove the material extending into the openings.

28. (Previously presented) A device for removing material from a vessel wall at a vascular site, comprising:

a sheath;

an expandable cage movable from a collapsed position to an expanded position, the cage forming a plurality of openings in the expanded position, the cage being configured such that when the cage is in the expanded position at the vascular site material from the vessel wall extends from the vessel wall into the openings, the expandable cage having an inner surface which defines a cavity, the expandable cage being contained within the sheath in the collapsed position so that

the sheath holds the cage in the collapsed position, the cage being releasable so that the cage may be left within the patient;

the sheath being retractable relative to the cage to expose the cage and permit the cage to expand; and

a material removing element positioned within the cage cavity to remove material from the vessel wall extending into the openings, the material removing element being positioned beneath the cage and being configured to be movable along the inner surface of the cage to remove the material extending into the openings.

29. (Original) The device of claim 28, wherein:

the cage has rigidly connected elements which form the openings, the rigidly connected elements being deformed when moved from the expanded position to the collapsed position.

30. (Original) The device of claim 28, wherein:

the rigidly connected elements are deformed within an elastic range when moving from the expanded position to the collapsed position.

31. (Original) The device of claim 28, further comprising:

a collapsible bag positioned to receive the material removed by the material removing element.

32. (Original) The device of claim 31, wherein:

the bag is coupled to the material removing element.

33. (Original) The device of claim 28, wherein:
the cage forms 2-10 openings.

34. (Original) The device of claim 28, wherein:
the openings have a length of at least 1 mm.

35. (Original) The device of claim 28, wherein:
the openings have a size of at least 0.5 mm.

63. (Previously presented) The device of claim 16, further comprising:
a collapsible bag positioned to receive the material removed by the material removing element.

64. (Previously presented) The device of claim 63, wherein:
the bag is coupled to the material removing element.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.